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(b) The entity must maintain an accurate, current inventory of each select agent and toxin held. The inventory records must include the following information for each select agent and toxin:

(1) The name, characteristics, and source data;

(2) The quantity held on the date of the first inventory (toxins only);

(3) The quantity acquired, the source, and date of acquisition;

(4) The quantity, volume, or mass destroyed or otherwise disposed of and the date of each such action;

(5) The quantity used and date(s) of the use (toxins only);

(6) The quantity transferred, the date of transfer, and individual to whom it was transferred (this includes transfers within an entity when the sender and the recipient are covered by the same certificate of registration);

(7) The current quantity held (toxins only);

(8) Any select agent or toxin lost, stolen, or otherwise unaccounted for; and

(9) A written explanation of any discrepancies.

(c) The entity must maintain the following records:

(1) For access to the select agents or toxins:

(i) The name of each individual who has accessed any select agent or toxin;

(ii) The select agent or toxin used;

(iii) The date when the select agent or toxin was removed, if removed from long-term storage or holdings for stock cultures;

(iv) The quantity removed (toxins only);

(v) The date the select agent or toxin was returned to the long-term storage or holdings for stock cultures; and

(vi) The quantity returned (toxins only);

(2) For access to the area where select agents are used or stored:

(i) The name of each individual who has accessed the area;

(ii) The date and time the individual entered the area;

(iii) The date and time the individual left the area; and

(iv) For individuals not approved under §73.8, the individual approved under §73.8 who accompanied the unapproved individual into the area.

(d) The entity must implement a system to ensure that all records and databases created under paragraphs (b) and (c) of this section are accurate, and that the authenticity of records may be verified.

(e) The entity must create a record concerning inspections conducted under §73.10(b).

(f) Safety, security, and emergency response plans.

(g) Training records.

(h) Transfer documents (CDC Form EA–101) and permits.

(i) Safety and security incident reports.

(j) The entity must maintain all records created under this part for three years.

§ 73.16 Inspections.

The HHS Secretary, without prior notification and with or without cause, shall be allowed to inspect any site at which activities regulated by this part are conducted and shall be allowed to inspect and copy any records relating to the activities covered by this part.

§ 73.17 Notification for theft, loss, or release.

(a) Upon discovery of a theft or loss of a select agent or toxin, an entity required to register under this part must immediately notify the HHS Secretary and State and local law enforcement. The notification must be reported to the HHS Secretary by either telephone, facsimile, or e-mail in accordance with §73.21.

(b) Thefts or losses must be reported whether the select agent or toxin is subsequently recovered or the responsible parties are identified.

(c) When reporting a theft or loss, the entity must provide the following information:

(1) The name of the select agent or toxin and any identifying information (e.g., strain or other characterization information);

(2) An estimate of the quantity lost or stolen;

(3) An estimate of the time during which the theft or loss occurred; and

(4) The location (building, room) from which the theft or loss occurred.

(d) The entity shall immediately notify the HHS Secretary and State and local public health agencies of any release of a select agent or toxin causing occupational exposure or release outside of the primary containment barriers. The report must be made to the HHS Secretary by telephone, facsimile, or e-mail in accordance with § 73.21.

(e) When reporting a release, the entity must provide the following information:

(1) The name of the select agent or toxin and any identifying information (e.g., strain or other characterization information);

(2) An estimate of the quantity released;

(3) The time and duration of the release;

(4) The environment into which the release occurred (e.g., in building or outside of building, waste system);

(5) The location (building, room) from which the release occurred;

(6) The number of individuals potentially exposed at the facility.

(7) Actions taken to respond to the release; and

(8) Hazards posed by the release.

(f) Within seven calendar days of theft, loss, or release, the entity must submit a follow-up report in writing to the HHS Secretary on CDC Form 0.1316 in accordance with § 73.21.

§ 73.18 Administrative review.

An entity may obtain review of a decision denying or revoking a certificate of registration under § 73.7 and the affected entity or individual may obtain review of a decision denying or revoking approval under § 73.8 by requesting such review in writing within 30 calendar days after the adverse decision. The request for review must state the factual basis for the review, which will be carried out in accordance with 42 U.S.C. 262a(e)(7). Where the adverse decision is in whole or in part based upon notification by the Attorney General under 42 U.S.C. 262a (e)(3), the request for review will be forwarded to the Attorney General for the Attorney General's review and final notification to the HHS Secretary.

§ 73.19 Civil money penalties.

(a) The Inspector General of the Department of Health and Human Services is delegated authority to conduct investigation and to impose civil money penalties against any individual or entity in accordance with regulations in 42 CFR part 1003 for violation of the regulations in this part, as authorized by the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (Public Law 107–188). The delegation of authority includes all powers contained in section 6 of the Inspector General Act of 1978 (5 U.S.C. App.).

(b) The administrative law judges in, assigned to, or detailed to the Departmental Appeals Board (DAB) have been delegated authority to conduct hearings and to render decisions with respect to the imposition of civil money penalties, as authorized by the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (Public Law 107–188). This delegation includes, but is not limited to, the authority to administer oaths and affirmations, to subpoena witnesses and documents, to examine witnesses, to exclude or receive and give appropriate weight to materials and testimony offered as evidence, to make findings of fact and conclusions of law, and to determine the civil money penalties to be imposed.

(c) The DAB of the Department of Health and Human Services is delegated authority to make final determinations with respect to the imposition of civil money penalties for violations of the regulations of this part.

§ 73.20 Criminal penalties.

The Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (Public Law 107–188) provides specific criminal penalties for violation of provisions of this part. This is in addition to any other criminal penalties that would apply for violation of provisions of this part.

§ 73.21 Submissions and forms.

(a) CDC forms referred to in this part, including registration application packages, may be obtained on the Select Agent Program Web site at *http://www.cdc.gov,* or by requesting them in